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VIA ECF AND EMAIL

MEMO ENDORSED

Hon. Katherine Polk Failla
United States District Court
Southern District of New York
New York, NY 10111

Re: *Nurture, LLC v. PBM Nutritionals, LLC*, No. 1:24-cv-02390-KPF-GS (S.D.N.Y.)

Dear Judge Failla:

Plaintiff Nurture, LLC ("Nurture") hereby responds to Defendant PBM Nutritionals, LLC's ("Perrigo's") January 27, 2024 letter seeking a pre-motion conference on its anticipated motion to quash or for a protective order regarding Nurture's subpoena to the Food & Drug Administration ("FDA"). *See* Dkt. 55. Perrigo's attempt to prevent FDA compliance with the subpoena should be rejected for multiple reasons.

As a threshold, and dispositive, matter, this Court is not the proper forum for a motion to quash by Perrigo. Rule 45(d)(3) is clear—a motion to quash or modify a subpoena should be filed in "the court for the district where compliance is required." Here, the subpoena commands the FDA's Division of Headquarters Freedom of Information to produce documents in Washington, D.C., within 100 miles of its place of business (in Rockville, Maryland). That is a proper place of compliance under Rule 45(c)(2)(A). "Thus, while this Court [the S.D.N.Y.] was properly named as the issuing court, it is not the proper court to receive . . . [the] motion to quash." *Arrowhead Cap. Fin., Ltd. v. Seven Arts Ent., Inc.*, 2021 WL 411379, at *2 (S.D.N.Y. Feb. 5, 2021) (Failla, J.). Under the plain language of Rule 45, to the extent that Perrigo has standing to move to quash the subpoena, it must do so in the United States District Court for the District of Columbia.

Perrigo's alternative motion for a protective order would not fix this jurisdictional defect. A party typically cannot sidestep Rule 45's requirements "simply by changing the name of the motion" from motion to quash to motion for a protective order. *See Bryant ex rel. Bryant v. Milhorat*, 2012 WL 13109865, at *1 (E.D.N.Y. May 15, 2012) (holding that motion for protective order is unavailable where the court is not a proper venue for a motion to quash). For these reasons alone, the Court should deny Perrigo's request for a pre-motion conference.

If the Court nevertheless considers Perrigo's objections to the subpoena, it should reject each of them. ***First***, Perrigo's argument that it has standing to quash the subpoena because it demands "competitively sensitive and proprietary information" is unavailing. The Court has entered a Confidentiality Stipulation and Protective Order (Dkt. 51), pursuant to which any such information of Perrigo can be protected through confidentiality designations by the FDA,

including "Attorney's Eyes Only" and "Outside Counsel Only" designations applicable to competitively sensitive and trade secret information. *See Albany Molecular Rsch., Inc. v. Schloemer*, 274 F.R.D. 22, 26 (D.D.C. 2011) (denying a motion to quash a subpoena to FDA, reasoning that the protective order would sufficiently safeguard the confidentiality of the requested information). Moreover, as Perrigo concedes, Subpoena Requests 8-10 seek information that is not related to Perrigo and thus does not implicate Perrigo's asserted confidentiality concerns. *A fortiori*, Perrigo does not have standing to move to quash these requests in any forum.

Second, Perrigo's assertion that Requests 5 and 7[1] of the subpoena are an "end-run" around the Court's October 3 rulings (Dkt. 55, at 2) is untrue. Perrigo mischaracterizes those rulings as wholly denying Nurture's motion to compel documents concerning Perrigo's other plants and other customers on grounds of "relevancy and proportionality." To the contrary, the Court found that the information Nurture requested is relevant, but also found that, as drafted, Nurture's requests were too broad and therefore likely to impose an undue burden on Perrigo. Dkt. 42, 10/03 Hr'g Tr. 48:2-15. Indeed, the Court expressly stated that Nurture could submit "more surgical" requests targeting the relevant information. *Id.* at 50:9-17. Simply stated, had the Court determined the requested information was not relevant, it would not have permitted Nurture to propound narrowed requests.

Moreover, at the October 3 conference, the Court **granted in full** Nurture's motion to compel Perrigo to produce, **for all Perrigo plants:** (1) all documents concerning any FDA inspections and/or other regulatory and/or enforcement activities concerning Perrigo's production of infant formula, and Perrigo's response to any such inspections, reviews, and/or other regulatory and/or enforcement activities (**Nurture's First RFP Request No. 14**); and (2) all documents Perrigo disclosed to the FDA regarding its infant formula production (**Nurture's First RFP Request No. 15**). *See* Dkt. 42, 10/03 Hr'g Tr. 40:25–50:8 ("What I'm willing to grant . . . [are] Requests 14 and 15, the materials regarding FDA inspections or federal, state, and local agency inspections for the time period from 2018 forward . . . I am granting that.").

Furthermore, to the extent that this Court denied any of Nurture's document requests directed at Perrigo on grounds of burden, such arguments have no applicability here since the FDA's production of the material will impose no burden on Perrigo.

Third**,** despite Perrigo's assertion that the documents sought from the FDA in Subpoena Requests 1-7 "have already been or will be produced" (Dkt. 55, at 3), Nurture has yet to locate a single Form FDA-483 or Warning Letter directed to Perrigo in Perrigo's document production—23 days past the parties' agreed-upon substantial completion deadline of January 7, 2025 (*See* Dkt. 49, at 3)—even though Perrigo is known to have received them. Further, because Perrigo has limited its document collection to a small set of custodians, there is no way to determine

[1] Request 5 seeks "All sanitation records submitted by Perrigo Relating to infant formula production, including but limited to, the sanitation records referenced in the FDA's August 30, 2023 Warning Letter to Perrigo Wisconsin, LLC." Request 7 seeks "All communications with Perrigo Relating to Form FDA-483s, Warning Letters, Untitled Letters, or Exceptional Release/Unblock Request Forms or concerning any subjects discussed within, including any communications between Perrigo and Center for Food Safety and Applied Nutrition."

what may go uncollected by Perrigo. To ensure that this highly probative information is obtained before the close of discovery, Nurture has sought the information directly from the FDA.

Fourth, Perrigo's argument that Subpoena Requests 9 and 10 should be quashed because information regarding the FDA's shutdown of Abbott's infant formula facility may be too prejudicial to be admissible at trial only highlights the relevance of the information to Nurture's claims.[2] Nurture is entitled to seek information in discovery that pertains to, e.g., the standard of care applicable to infant formula manufacturing, and the infant formula shortages to which the Abbott shutdown contributed. Theoretical disputes regarding the admissibility at trial of such information have no bearing on discoverability. Fed. R. Civ. P. 26(b)(1) ("Information within this scope of discovery need not be admissible in evidence to be discoverable."); *cf. Edwards v. Middleton*, 2021 WL 961762, at *3 (S.D.N.Y. Mar. 15, 2021) ("as the scope of inquiry for discovery is generally broader than the test for admissibility at trial, Defendant's hearsay objections are premature").

Fifth, although Perrigo generally objects to Subpoena Request 8, it provides no basis for quashing this request. Request 8 seeks information regarding the time and steps involved in obtaining FDA approval to sell infant formula. This information is directly relevant to rebutting Perrigo's affirmative defense that Nurture allegedly failed to mitigate its damages. To the extent that Perrigo intends to argue that Nurture should have obtained FDA approval to manufacture its own infant formula so that it did not need to rely on Perrigo, Nurture plans to adduce evidence of the lengthy and difficult process that such an effort entails. Nurture is therefore seeking such information directly from the source—the FDA.

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Because Perrigo's anticipated motion is fatally flawed, procedurally and substantively, Nurture respectfully submits that a pre-motion conference is unnecessary.

Respectfully submitted,

/s/ Denise L. Plunkett

Denise L. Plunkett

cc: All counsel of record (by ECF and email)

[2] As noted above, Perrigo tacitly concedes it does not have standing to challenge Requests 8-10. Perrigo's only argument that it has standing to quash the subpoena is that it "seeks proprietary, confidential, and protected information sensitive *to Perrigo*." Dkt. 55, at 2 (emphasis added). However, that argument has no application to Request 8, which concerns the FDA's approval timeline and requirements, or Requests 9 and 10, which relate to "a different manufacturer (Abbott)." *Id.* at 3.

The Court has reviewed Defendant's pre-motion letter (Dkt. #55) and Plaintiff's letter in response (Dkt. #56). The Court will discuss the issues raised in these letters with the parties at a pre-motion conference to take place on **February 7, 2025**, at **11:00 a.m.**

The conference shall take place via telephone. At the scheduled time, the parties shall dial (855) 244-8681 and enter access code 2315 780 7370.

The Clerk of Court is directed to terminate the pending motion at docket entry 55.

Dated: January 31, 2025
New York, New York

SO ORDERED.

Katherine Polk Failla

HON. KATHERINE POLK FAILLA
UNITED STATES DISTRICT JUDGE